

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

ABBOTT GMBH & CO., KG,)	
ABBOTT BIORESEARCH CENTER, INC.,)	C.A. No. 4:09-CV-11340 (FDS)
and ABBOTT BIOTECHNOLOGY LTD.,)	
)	
Plaintiffs,)	JURY TRIAL DEMANDED
)	
v.)	
)	
CENTOCOR ORTHO BIOTECH, INC. and)	
CENTOCOR BIOLOGICS, LLC.,)	
)	
Defendants.)	

**CENTOCOR’S REPLY MEMORANDUM
ON THE ISSUE OF WILLFUL INFRINGEMENT**

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I. SUMMARY OF ARGUMENT IN REPLY

Abbott seeks to alter the procedure that this Court has already ruled would govern the determination of willful infringement. Rather than have the Court rule on the issue of objective recklessness as a threshold legal issue, Abbott again asks the Court to submit the entire willfulness issue to the jury. But Abbott's approach is counter to the Federal Circuit's *Bard* decision, as well as numerous post-*Bard* district court cases. The Court should not alter its ruling that it will decide the objective prong of the *Seagate* test following the first phase of the trial.

With regard to the merits of Abbott's willfulness claims, Abbott's position is that every one of Centocor's defenses is so weak that no reasonable litigant could ever expect to prevail. If that were really the case, surely Abbott would have moved for summary judgment disposing of the entire action. It did not. The reason it did not, and could not, is because Centocor's defenses are entirely credible. Abbott cannot meet its heavy burden of proving objective recklessness by clear and convincing evidence.

II. ABBOTT'S ATTEMPT TO ALTER THE COURT'S RULING ON THE SEQUENCING OF TRIAL SHOULD BE REJECTED

During its July 16, 2012 status conference, the Court bifurcated trial so that it could consider the threshold issue of objective recklessness prior to potentially submitting the subjective prong of the *Seagate* test to the jury for determination. In fact, the purpose of this very briefing is to provide the Court with an understanding of the issues so that it can decide the legal issue of objective recklessness pursuant to the *Bard* case following the first phase of trial. Abbott now asks the Court *not* to rule on objective recklessness, but rather to submit the entire issue to the jury. That proposal should be rejected as it not only ignores the Court's prior ruling and the entire reason for bifurcation to begin with, but it is counter to both the *Bard* decision and the procedures that other district courts are following post-*Bard*.

Abbott argues that the *Bard* decision “does not impose a procedure for **trying** willfulness; it clarifies the standard of **reviewing** willfulness determinations” (Abbott Br. at 15) (emphasis in original). Abbott’s argument, however, ignores one very important word in the Federal’s Circuit’s willfulness jurisprudence – **threshold**. The Federal Circuit’s en banc decision was clear – the first prong of the *Seagate* test is a “**threshold** objective standard.” *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*) (emphasis added). The *Bard* court, of course, said the very same thing and clarified that “the **threshold** objective prong . . . is a question of law” for the court. *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 1005 (Fed. Cir. 2012) (emphasis added).

Post-*Bard* Federal Circuit case law makes clear that, contrary to Abbott’s arguments, *Bard* does not merely clarify a standard for reviewing willfulness determinations; it necessarily imposes a procedure for trying willfulness. For example, in *Highmark, Inc. v. Allcare Health Mgmt. Sys., Inc.*, a case relied on by Abbott in its brief,¹ the court expressly stated that the objective prong is a threshold **determination** that is to be made by the district court, not the jury:

We have recently clarified that “the threshold objective prong . . . is a question of law based on underlying mixed questions of law and fact and is subject to *de novo* review.” *Bard Peripheral Vascular, Inc. v. W.L. Gore & Assocs., Inc.*, 682 F.3d 1003, 2012 WL 2149495, at *1 (Fed. Cir. 2012); *see also Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1236 (Fed. Cir. 2011). **That determination must be made by the court as a matter of law rather than by the jury.**

No. 2011-1219, 2012 U.S. App. LEXIS 16450, at *11 (Fed. Cir. 2012) (emphasis added) (Ex. 10). Nowhere does the Court state or suggest that, as Abbott argues, the threshold objective prong is to be “reviewed” – and not determined in the first instance – by the district court.

¹ Although *Highmark* is not listed in Abbott’s Table of Authorities, the case is cited on at least pages 3, 15, and 16 of Abbott’s brief.

Since *Bard*, numerous district courts have determined, as this Court has, that they must rule on the objective prong as a matter of law ***before*** submitting the subjective prong to the jury. For example, in *Sargent Mfg. Co. v. Cal-Royal Prods.*, No. 3:08-cv-408 (VLB), 2012 U.S. Dist. LEXIS 105260, at *4 (D. Conn. July 27, 2012) (Ex. 11), the district court determined that “combining the instructions set forth in both *Seagate* and *Bard*, it is clear that the objective prong of the willfulness analysis is a ***threshold issue which must be satisfied before advancing to consider the subjective prong.***” *Id.* at *4 (emphasis added). “If . . . the Court finds that the objective recklessness prong has been satisfied, the Court will then present the question of subjective recklessness to the jury along with the remainder of the case.” *Id.* at *5. Similarly, the district court in *BASF Corp. v. Aristo, Inc.*, 2:07 CV 222 PPS, 2012 U.S. Dist. LEXIS 90768, at *7 (N.D. Ind. June 29, 2012) (Ex. 12) held that “[a]ccording to *Bard*, a willfulness determination should be sent to the jury only when a judge has decided, as a matter of law, that there is clear and convincing evidence that a defendant's conduct in using an allegedly patented process was objectively reckless.”

Abbott’s attempt to analogize the willful infringement determination to obviousness and enablement – both questions of law with underlying fact issues – does not help its argument. Neither obviousness nor enablement has a “threshold” issue as willful infringement does. The “threshold” objective determination for willful infringement is more similar to the “threshold” determination of claim construction in a patent infringement analysis – also a legal issue with underlying fact issues – which must be completed by the district court prior to the submission of the infringement issue to the jury. *See Athletic Alternatives v. Prince Mfg.*, 73 F.3d 1573, 1578 (Fed. Cir. 1996) (the first step in a patent infringement analysis is “the threshold construction of the meaning and scope of the asserted claim”); *see also MBO Labs., Inc. v. Becton, Dickinson &*

Co., 783 F. Supp. 2d 216, 220 (D. Mass. 2011). Just as this Court determined the “threshold” legal issue of claim construction, the Court must also determine the “threshold” legal issue of objective recklessness issue prior to potentially submitting the subjective prong to the jury.

Abbott also argues that Centocor’s proposed jury instruction on willfulness supports its position that the jury should make a determination of both the subjective and objective prongs (Abbott Br. at 17-18). This argument is nonsensical as both parties have submitted a proposed jury instruction that does *not* instruct the jury on the objective prong, but only the subjective prong. How Centocor’s submission of a proposed instruction only on the *subjective* prong shows support for the idea that the jury should also consider the *objective* prong is a mystery to Centocor.

Abbott’s attempt to have this Court disregard the Federal Circuit’s holdings in cases like *Seagate* and *Bard* should be rejected.

III. ABBOTT CANNOT SHOW THAT CENTOCOR’S DEFENSES ARE OBJECTIVELY UNREASONABLE

In an effort to heed the Court’s instruction to keep reply briefs on the issue of willfulness short and concise, Centocor will very briefly reply regarding three of its primary defenses – written description, enablement, and obviousness. Other Centocor defenses such as noninfringement and anticipation by prior invention were discussed at length in Centocor’s opening memorandum. And some defenses mentioned in Centocor’s opening brief (*e.g.*, lack of written description of the “p19” claims and noninfringement of the “Kd” claims) are no longer relevant as, subsequent to the filing of opening briefs on this issue, Abbott has indicated that it is no longer asserting those claims. The failure to address any particular defense or any particular Abbott argument should not be read as a concession by Centocor of “unreasonableness.”

A. Centocor's Written Description Defense Is Reasonable

Abbott argues that there is sufficient written description in its patents because they purportedly disclose “50 representative antibodies” (Abbott Br. at 7). The problem with Abbott’s “50 representative antibodies” argument is that every single antibody is nothing more than a small variation of *one antibody* – the Joe 9 antibody. Abbott cannot point to a single antibody in its specification that is *not* part of the closely-related Joe 9 family. Thus, regardless of their number, the disclosed antibodies are not “representative” of the broad genus that Abbott claims.

Abbott’s also argues that “Centocor has not provided any substantial evidence that Abbott’s claimed genus is substantially larger or more diverse than the antibodies disclosed in Abbott’s patents” (Abbott Br. at 8-9). But one needs to look no further than Centocor’s accused Stelara product to understand that there is ample evidence that Abbott’s claimed genus is *much* more diverse than what is actually disclosed in the patent. Stelara is dramatically different than the disclosed Joe 9 antibodies. Stelara has a much different sequence from the Joe 9 antibodies, it binds to a different epitope on IL-12, and, even though the patents note the importance of having a V_H3 heavy chain as all the disclosed antibodies do, Stelara has a V_H5 heavy chain. Abbott’s alleged disclosure of “50 antibodies” all stemming from the Joe 9 lineage is hardly “representative” of the broad genus that includes Stelara. *See Carnegie Mellon Univ. v. Hoffman-La Roche, Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008) (patent must describe a *sufficient variety* of species of a varied genus).

Moreover, Abbott’s argument that Centocor’s written description defense is “unreasonable” simply because it was not raised in the interference is disingenuous. Abbott knows full well that the PTO proceeding provides nowhere near the level of discovery and information exchange as does a district court litigation. Nothing can and should be read into the

“reasonableness” of Centocor’s defenses from whether or not they were raised in administrative proceeding before the Board of Patent Appeals – as opposed to a district court jury trial.

Centocor’s written description is more than reasonable. Because this defense covers every asserted claim in this case, it alone precludes a finding of objective recklessness.

B. Centocor’s Enablement Defense Is Reasonable

Abbott’s counter-arguments on enablement are identical to its arguments on written description. Because there are purportedly “50 antibodies” disclosed in its patents, Abbott contends that this somehow teaches one of skill in the art to make and use the full scope of the claimed invention. Once again, however, the Stelara antibody itself shows that Abbott’s arguments fail.

Stelara includes a V_H5 heavy chain and was made by transgenic mouse technology. Abbott’s patents fails to provide the necessary teachings regarding an antibody having *either one of these characteristics*. Abbott’s patents teach antibody production through phage display methods by use of a phage display library, but there is no evidence that this library would *ever* produce a V_H5 antibody. Moreover, the specification’s entire teaching on transgenic mouse technology is the mention of a single prior art reference. That, of course, is entirely insufficient. *See, e.g., Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366 (Fed. Cir. 1997) (application, not the knowledge of a person of skill in the art, “must supply the novel aspects of an invention in order to constitute adequate enablement”).

There is simply no teaching in Abbott’s patent about how to make and use anything remotely resembling the Stelara antibody and, accordingly, the patents should be held invalid for lack of enablement. This defense, which covers all asserted claims, is more than reasonable.

C. Centocor's Obviousness Defense Is Reasonable

Abbott's counter-argument on obviousness is that Centocor's defense cannot be reasonable because it did not carry the day in the interference. That argument, however, ignores the vast amount of discovery taken in this litigation that was never presented to the Board of Patent Appeals, as well as the Board's acknowledgement that it was deciding obviousness largely based on a credibility determination between two experts, neither of whom is testifying in this case (Ex. 13, Interference Paper No. 418 at 37-38).

Abbott's remaining arguments also do nothing to show that Centocor's obviousness defense is unreasonable. For example, Abbott makes the nonsensical argument that the claims are nonobvious because "some of" the Abbott inventors were awarded a prize related to their work on a project *unrelated to IL-12 antibodies* (Abbott Br. at 11). Centocor is unaware of any support for Abbott's contention that evidence of non-obviousness includes an inventor's receipt of a prize for work *unrelated* to what is shown in the patent. Coincidentally, Abbott fails to mention that it was actually *Centocor* that was awarded the prize in 2011 for its discovery of Stelara (Ex. 14, 2011-09-28 Press Release).

In the end, the evidence will show that Abbott's claimed invention is obvious because creating an antibody with the functional properties set forth in Abbott's asserted claims would have been the predictable result of applying established methods to make and improve the properties of human antibodies to IL-12. Centocor's obviousness defense is a reasonable one.

IV. CONCLUSION

If necessary following the conclusion of the first phase of trial, the Court should hold that Centocor's reasonable defenses preclude a finding of objective recklessness. If the Court is not prepared to rule at that time that Centocor's defenses were reasonable, Centocor requests oral argument before the Court makes its final determination on objective recklessness.

September 4, 2012

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the foregoing **CENTOCOR'S REPLY MEMORANDUM ON THE ISSUE OF WILLFUL INFRINGEMENT** was electronically mailed to counsel of record on September 4, 2012.

/s/Angela Verrecchio_____